

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION**

NESTLÉ HEALTH SCIENCE - PAMLAB,
INC. AND BRECKENRIDGE
PHARMACEUTICAL, INC.

Plaintiffs,

v.

METHOD PHARMACEUTICALS, LLC,

Defendant.

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Case No. 3:15-cv-1660

JURY TRIAL DEMANDED

ORIGINAL COMPLAINT

Nestlé Health Science – PamLab, Inc. and Breckenridge Pharmaceutical, Inc. (collectively, “Plaintiffs”), by and through their attorneys, hereby state as follows for their Complaint against Defendant Method Pharmaceuticals, LLC:

I. THE PARTIES

1. Nestlé Health Science – PamLab, Inc. (“NHS”) is a Delaware corporation with its principal place of business at 4099 Highway 190, Covington, Louisiana 70433.

2. Plaintiff Breckenridge Pharmaceutical, Inc. (“Breckenridge”) is a Florida corporation with its principal place of business at 6111 Broken Sound Parkway, Suite 170, Boca Raton, Florida 33487.

3. Defendant Method Pharmaceuticals, LLC (“Method”) is a Texas limited liability company with its principal place of business at 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006. Method may be served with process by serving a copy of the Original Complaint on its Registered Agent for service of process: United States Corporation Agents, Inc., located at 9900 Spectrum Drive, Austin, Texas 78717.

II. JURISDICTION AND VENUE

4. This is an action for false advertising and unfair competition under section 43 of the Lanham Act, Title 15 of the United States Code § 1125, and/or common law unfair competition in Texas and other states in which Defendant is conducting its activities. This Court has original jurisdiction over the subject matter of this lawsuit under 28 U.S.C. §§ 1331, 1332 and 15 U.S.C. § 1121(a), because it arises under the Lanham Act. Additionally, the amount in controversy exceeds \$75,000 and involves citizens of different states.

5. This Court has jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367 and the doctrine of supplemental jurisdiction, because the subject matter is so related to the claims asserted under federal law as to form part of the same case or controversy.

6. The exercise of personal jurisdiction in Texas is proper as acts giving rise to Plaintiffs' causes of action have occurred in the State of Texas, Defendant is a Texas limited liability company, and its principal place of business is 2000 East Lamar Boulevard, Suite 600, Arlington, Texas 76006.

7. Venue is proper in this Court under 28 U.S.C. § 1391(d).

III. FACTUAL BACKGROUND

A. Plaintiff NHS and Its Medical Foods

8. Plaintiff NHS is a fully integrated pharmaceutical company, founded over 50 years ago, that specializes in the development of prescription medical foods that are marketed and sold nationally.

9. NHS markets its medical foods as a "brand" pharmaceutical company. As such, NHS markets its products directly to physicians educating those physicians concerning the benefits and appropriate uses of its medical food products. NHS has spent millions of dollars calling on tens of thousands of physicians through NHS's sales force, providing millions of

product samples, publishing articles and advertisements in medical journals, and funding clinical studies.

10. As described in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. § 360ee(b)(3)), a “medical food” is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” As a therapeutic category, medical foods are distinct from both drugs and dietary supplements.

11. NHS produces four medical foods that are relevant to this lawsuit: Cerefolin NAC[®], Deplin[®] (in 7.5 mg and 15 mg dosages), and Metanx[®] (collectively, the “NHS Products”). The NHS Products are medical foods that have been formulated to provide the biologically active form of “folate,” to meet the distinct nutritional requirements of patients with certain diseases and medical conditions that may benefit from such a formulation. The NHS Products are dispensed in response to a prescription.

12. The NHS Products provide the active, naturally occurring form of folate used by the body: 6(S)-5-Methyltetrahydrofolate, also called L-Methylfolate.

13. L-Methylfolate is a distinct compound from its diastereoisomer, D-Methylfolate. Many chemical compounds occur as mixtures of two or more diastereoisomers, which have the same chemical composition, but differ in the spatial arrangement of the atoms. The diastereoisomers may have very different properties from one another. In some cases, one diastereoisomer can have a therapeutic effect, while another diastereoisomer is therapeutically ineffective or even harmful. Thus, there are often great benefits to providing patients and consumers with a product that is diastereoisomerically pure (i.e. contains only a single diastereoisomer as opposed to a diastereoisomeric mixture).

14. Diastereoisomers are distinguished from one another through naming conventions that reflect their different properties. One such naming convention uses an “L” in the name of the compound to indicate one diastereoisomer, and a “D” in the name of the compound for a different diastereoisomer. The L-form of this compound used in the NHS Products – *i.e.*, L-Methylfolate – is superior to the D-form of this compound (D-Methylfolate) because the L-form is the naturally occurring predominant form of folate found in food and the human body. The L-form is the biologically active form of folate and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. The D-form, on the other hand, is of no benefit to humans.

15. L-Methylfolate can be synthesized in commercial quantities as an amorphous salt. However, in this form, it is highly unstable and degrades quickly, making it unsuitable for use in pharmaceutical products.

16. The NHS Products use Metafolin[®], a patented, crystalline form of L-Methylfolate. Metafolin[®] is a substantially diastereoisomerically pure source of L-Methylfolate that contains not more than 1% D-Methylfolate. This ingredient was accepted by the FDA as a food additive and is generally recognized as safe (GRAS). Unlike other forms of L-Methylfolate, Metafolin[®] is stable and suitable for use in pharmaceutical products. NHS uses the presence of the dietary ingredient L-Methylfolate (Metafolin[®]) as a primary selling point for its products.

B. The NHS-Breckenridge Joint Venture and the Authorized Generic Products

17. Plaintiff Breckenridge, in contrast to NHS, is a generic pharmaceutical company. For more than 25 years Breckenridge has been in the business of developing and marketing generic pharmaceutical products, and it currently markets more than 70 such products.

18. Breckenridge and NHS have entered into a Joint Venture wherein Breckenridge sells generic versions of the NHS Products, under authority from NHS. Breckenridge sells Metafolbic™ Plus RF, L-Methylfolate Forte (7.5 mg and 15 mg), and Foltax™ RF (the “Breckenridge Generic Products”), which correspond to Cerefolin NAC®, Deplin® (7.5 mg and 15 mg), and Metanx®, respectively. The NHS Products and the Breckenridge Generic Products may be referred to below, collectively, as “Plaintiffs’ L-Methylfolate Products.”

19. The Breckenridge Generic Products have the identical ingredients – including the same pure L-Methylfolate ingredient (Metafolin®) – in the same strengths as the corresponding NHS Products. NHS manufactures the Breckenridge Generic Products for Breckenridge in the same facility, using the same quality, purity and performance specifications it uses for the NHS Products. The Breckenridge Generic Products are identical in every way to the NHS Products except for imprint and labeling, and may be dispensed as substitutes for prescriptions written for the NHS Products. NHS and Breckenridge share in the profits generated by sales of the Breckenridge Generic Products.

C. Defendant’s Knock-Off L-Methylfolate Products

20. Method is a Texas-based, generic drug distributor that purports to develop, manufacture, market and sell what it calls “specialty pharmaceuticals.” On information and belief, Method does not market its pharmaceutical products to physicians. Rather, it convinces pharmaceutical wholesalers, distributors, pharmacies, pharmacists and national drug databases that its products are “generics” or substitutes for brand-name pharmaceutical products. Its sales result from “generic” substitution of its products for brand-name drugs.

21. On information and belief, Method promotes, markets, sells and distributes its products nationwide, including in Texas and this judicial district.

22. Sometime in 2014, Method saw an opportunity to exploit the reputation and success of Plaintiffs' L-Methylfolate Products by creating knock-off products (hereafter "Defendant's L-Methylfolate Products"). Defendant's L-Methylfolate Products include:

- Levomefolate Calcium/Acetylcysteine/Mecobalamin/Algal Powder Caplets (NDC No. 58657-202);
- Levomefolate Calcium/Algal Powder Capsules (7.5 mg) (NDC No. 58657-205);
- Levomefolate Calcium/Algal Powder Capsules (15 mg) (NDC No. 58657-208); and
- Levomefolate Calcium/Pyridoxal-5 Phosphate/Mecobalamin/Algal Powder Capsules (NDC No. 58657-211).

D. Method Markets Defendant's L-Methylfolate Products as containing the same ingredients in the same strength and as generic equivalents to the NHS Products

23. In its commercial advertising and promotion, including specifically its labels, package inserts and other documents (including documents provided to the FDA), Method claims Defendant's L-Methylfolate Products have the same ingredients, including "L-Methylfolate Calcium* (*CAS 151533-22-1), in the same strengths as Cerefolin NAC[®], Deplin[®] 7.5 mg, Deplin[®] 15 mg, and Metanx[®], respectively.

24. Upon information and belief, in its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others (the "pharmaceutical distribution chain"), Method has made no effort to differentiate Defendant's L-Methylfolate Products from the NHS Products other than on the basis of price. Instead, on information and belief, Method markets Defendant's L-Methylfolate Products to the pharmaceutical distribution chain as generic equivalents to and substitutes for the NHS Products. In furtherance of its promotional scheme, Method has had its knock-off products "linked" to the NHS Products as equivalents in drug databases that represent a major marketing communications channel to drug

wholesalers, pharmacies and others, and that are used by pharmacists to decide which product to dispense when filling a prescription.

25. Upon information and belief, Method seeks to capture market share from Plaintiffs' L-Methylfolate Products by encouraging generic substitution of Defendant's L-Methylfolate Products for prescriptions written by health care providers for the NHS Products.

26. Upon information and belief, Method's efforts have had their intended effect; based upon Method's commercial advertising and promotion, drug databases as well as wholesalers, pharmacies and others have linked Defendant's L-Methylfolate Products to the NHS Products as generic equivalents.

27. As a result of Defendant's commercial advertising and promotion, wholesalers and pharmacies in the Northern District of Texas and across the country have purchased or will purchase Defendant's L-Methylfolate Products and have ceased or will cease to purchase Plaintiffs' L-Methylfolate Products, believing that the Defendant's L-Methylfolate Products are available as generic substitutes. This could not occur unless Method had successfully created the false impression among drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain that Defendant's L-Methylfolate Products contain the ingredients in the same strengths as Plaintiffs' L-Methylfolate Products and that they are generic to and substitutable for the NHS Products.

E. Method Markets Defendant's L-Methylfolate Products as Drugs

28. The Drug Listing Act of 1972 requires registered drug companies to provide the FDA with a current list of all human drugs they manufacture or label for commercial distribution. These companies identify their drug products using a unique, three-segment number, called the National Drug Code (NDC). The FDA publishes information submitted by drug establishments about their drug products in the NDC Directory.

29. It is unlawful to assign an NDC number to a non-drug product.

30. Defendant Method claims its L-Methylfolate Products are drugs in the information it provides to the FDA. As a result, Defendant's L-Methylfolate Products are assigned NDC numbers and are identified in the FDA's NDC Directory as "human prescription drugs." For example, the NDC Directory lists Defendant's Levomefolate Calcium/Algal Powder Capsules (7.5 mg) as follows:

Method Pharmaceuticals, LLC 58657-205-90 Levomefolate Calcium and Algal (levomefolate calcium and schizochytrium dha oil) CAPSULE 7.5 mg/1, 90.314 mg/1
Product NDC: 58657-205 Proprietary Name: Levomefolate Calcium and Algal Non-Proprietary Name: levomefolate calcium and schizochytrium dha oil Product Type Name: HUMAN PRESCRIPTION DRUG Market Category Name: UNAPPROVED DRUG OTHER Application Number: Route Name: ORAL Substance Name: LEVOMEFOLATE CALCIUM; SCHIZOCHYTRIUM DHA OIL Package Description: 90 CAPSULE in 1 BOTTLE (58657-205-90) Pharm Class: N/A DEA: N/A Labeler Name: Method Pharmaceuticals, LLC Start date: 04-01-2015 / End date: N/A

The pharmaceutical distribution chain relies on information the FDA publishes in the NDC Directory to identify drugs eligible for insurance reimbursement. Governmental (e.g., Medicaid) and private insurers provide insurance coverage for many types of human prescription drugs. However, Medicaid and many private insurers do not cover medical foods such as the Plaintiffs' L-Methylfolate Products.

31. As a result of Defendant's commercial advertising and promotion through the NDC Directory and elsewhere, wholesalers and pharmacies in the Northern District of Texas and across the country have purchased or will purchase Defendant's L-Methylfolate Products and have ceased or will cease to purchase Plaintiffs' L-Methylfolate Products, believing that Defendant's L-Methylfolate Products are eligible for insurance reimbursement while Plaintiffs' L-Methylfolate Products are not. This could not occur unless Method had successfully created the false impression among drug databases, wholesalers, pharmacies, pharmacists and others in

the pharmaceutical distribution chain that Defendant's L-Methylfolate Products are human prescription drugs.

F. Method's Advertising is Literally False and Misleading

(a) Defendant's L-Methylfolate Products Do Not Have the Same Active Ingredients in the Same Amounts as Plaintiffs' L-Methylfolate Products

32. Notwithstanding Method's commercial advertising and promotion, Defendant's L-Methylfolate Products do not have the same active ingredients in the same amounts as Plaintiffs' L-Methylfolate Products.

33. Method does not use the same pure and stable L-Methylfolate ingredient used in Plaintiffs' L-Methylfolate Products. Instead, upon information and belief, Method utilizes an impure and unstable form of L-Methylfolate Calcium. Upon information and belief, the use of this impure and unstable ingredient in the manufacture of Defendant's L-Methylfolate Products leads to inferior, sub-standard and unstable finished products.

(b) Defendant's L-Methylfolate Products Are Not Generic Equivalents to or Substitutes for the NHS Products

34. A pharmacist presented with a doctor's prescription for a brand-name product may fill that prescription by dispensing the product prescribed or an identical, "generic" version of the product. This process is known as generic substitution.

35. A generic pharmaceutical product is identical – or bioequivalent – to a brand name product in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. It is the same as a brand-name product in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. It must have the same high quality, strength, purity and stability as the brand-name product.

36. Notwithstanding Method's express and implied representations in its commercial advertising and promotion, Defendant's L-Methylfolate Products are not generic equivalents to

or substitutes for Plaintiffs' L-Methylfolate Products because they do not have the identical L-Methylfolate ingredient, strength, quality, performance characteristics and/or intended use.

(c) Defendant's L-Methylfolate Products are Not Human Prescription Drugs that are Reimbursable

37. Notwithstanding Defendant's commercial advertising and promotion, Defendant's L-Methylfolate Products are not human prescription drugs eligible for reimbursement. Drugs are defined as:

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

Furthermore any "new" drug must be have an approved New Drug Application. Defendant's L-Methylfolate Products are not listed in the Homoeopathic Pharmacopoeia or the National formulary. Nor are they intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body. Defendant's L-Methylfolate Products are not the subject of an approved New Drug Application. Thus, Defendant's L-Methylfolate Products are not drugs.

COUNT I

**FALSE ADVERTISING IN VIOLATION OF
THE LANHAM ACT, 15 U.S.C. § 1125(A)**

38. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

39. In its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in interstate commerce, Method represents that Defendant's L-Methylfolate Products have the same ingredients in the same strength as Plaintiffs'

L-Methylfolate Products, are generics to and substitutes for Plaintiffs' L-Methylfolate Products, and are drugs. Method intends for drug databases, wholesalers, pharmacies, pharmacists and others to believe that Defendant's L-Methylfolate Products are equivalent to and substitutable for Plaintiffs' L-Methylfolate Products, and to purchase Defendant's L-Methylfolate Products in place of Plaintiffs' L-Methylfolate Products. Method further intends drug databases, wholesalers, pharmacies, pharmacists and consumers to believe that Defendant's L-Methylfolate Products are eligible for reimbursement by governmental and private insurers.

40. Method's promotional claims about Defendant's L-Methylfolate Products are literally and/or impliedly false and misleading. Defendant's L-Methylfolate Products do not have the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products; they are not equivalent to, generic to, or substitutable for Plaintiffs' L-Methylfolate Products, and they are not drugs eligible for reimbursement. Method's promotional claims violate Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), which provides in relevant part that

any person who, on or in connection with any goods or services, . . . uses in commerce any . . . false or misleading description of fact or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable to a civil action by any person who believes that he or she is likely to be damaged by such act.

41. Additionally, Method is liable for false advertising under the Lanham Act because Method intentionally induced and/or knew or had reason to know that the government, drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain would falsely describe Defendant's L-Methylfolate Products as having the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, as generic to and substitutable for Plaintiffs' L-Methylfolate Products, and as drugs to pharmacists, but continued to market and sell the products to those entities.

42. Upon information and belief, Method has also made other false and/or misleading representations of fact that misrepresent the nature, characteristic, or qualities of Defendant's L-Methylfolate Products.

43. Method's false and misleading explicit and/or implicit representations go to an inherent quality or characteristic of Defendant's L-Methylfolate Products. Thus, Method's false and misleading explicit and/or implicit representations are material, have influenced or will influence purchasing decisions in this District and elsewhere, and will continue to do so unless enjoined.

44. By reason of Method's conduct, Plaintiffs have suffered or are likely to suffer, damage to their business, reputations, and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of Defendant's L-Methylfolate Products, and recovery of Plaintiffs' costs for this action.

45. Method's acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

46. Unless enjoined by this Court, Defendant Method's acts will irreparably injure Plaintiffs' goodwill and erode their market share. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendant Method's continuing acts.

47. Upon information and belief, Defendant Method will continue its violation of the Lanham Act unless this violation is restrained and enjoined by this Court. Due to Defendant Method's continuing acts of false advertising, Plaintiffs have suffered and/or will suffer irreparable injury for which they have no adequate remedy at law.

COUNT II
**UNFAIR COMPETITION IN VIOLATION OF
THE LANHAM ACT, 15 U.S.C. § 1125(A)**

48. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

49. Plaintiffs have become uniquely associated with the Plaintiffs' L-Methylfolate Products, and the public identifies Plaintiffs as the source for Plaintiffs' L-Methylfolate Products.

50. In its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in interstate commerce, Method represents that Defendant's L-Methylfolate Products have the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, are generics to and substitutes for Plaintiffs' L-Methylfolate Products, and are drugs. In doing so, Method has deceived, misled, and confused drug databases, wholesalers, pharmacies, pharmacists and consumers as to the nature, characteristics and qualities of Defendant's L-Methylfolate Products in comparison, connection or association with Plaintiffs' L-Methylfolate Products. This has enabled Method to trade off of Plaintiffs' reputation and good will.

51. Method's acts constitute unfair competition in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

52. Additionally, Method is liable for unfair competition under the Lanham Act because it intentionally induced and/or knew or had reason to know that the government, drug databases, wholesalers, pharmacies, pharmacists and others in the pharmaceutical distribution chain falsely describe Defendant's L-Methylfolate Products as having the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, as generic to and substitutes for the Plaintiffs' L-Methylfolate Products, and as drugs to pharmacists, but continued to market and sell the products to those entities.

53. By reason of Method's conduct, Plaintiffs have suffered or are likely to suffer, damage to their business, reputations, and goodwill. Pursuant to 15 U.S.C. § 1117, Plaintiffs are entitled to damages for Defendant's Lanham Act violations, an accounting of profits made by Defendant on sales of Defendant's L-Methylfolate Products, and recovery of Plaintiffs' costs for this action.

54. Defendant's acts are willful, wanton and calculated to deceive, and are undertaken in bad faith, making this an exceptional case entitling Plaintiffs to recover additional damages and reasonable attorneys' fees pursuant to 15 U.S.C. § 1117.

55. Unless enjoined by this Court, Defendant's acts will irreparably injure Plaintiffs' goodwill and erode its market share. Pursuant to 15 U.S.C. § 1116, Plaintiffs are entitled to preliminary and permanent injunctive relief to prevent Defendant's continuing acts.

COUNT III
COMMON LAW UNFAIR COMPETITION

56. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

57. With full knowledge of Plaintiffs' L-Methylfolate Products, Defendant Method made false and misleading explicit and implicit representations in its commercial advertising and promotion to drug databases, wholesalers, pharmacies, pharmacists and others in interstate commerce, that Defendant's L-Methylfolate Products have the same ingredients in the same strength as Plaintiffs' L-Methylfolate Products, are generics to and substitutes for Plaintiffs' L-Methylfolate Products, and are drugs.

58. Defendant Method's false and misleading statements and omission of relevant facts are likely to cause and have caused confusion, mistake or deception about the nature,

characteristics and qualities of Defendant's L-Methylfolate Products in comparison, connection or association with Plaintiffs' L-Methylfolate Products.

59. Defendant knows, or in the exercise of reasonable discretion should know, that its advertising deceives potential customers about the nature, characteristics and qualities of Defendant's L-Methylfolate Products in comparison, connection or association with Plaintiffs' L-Methylfolate Products.

60. Defendant Method's conduct amounts to deception, trickery and/or unfair methods and has damaged and jeopardized Plaintiffs' businesses. As a result of such malicious, wanton and/or fraudulent conduct, Defendant has caused, will cause, and unless enjoined by the Court, will continue to cause confusion as to the substitutability for and equivalence of its knockoff products with Plaintiffs' L-Methylfolate Products.

61. Plaintiffs are entitled to damages for Defendant Method's unfair competition, an accounting of profits made on sales of Defendant's L-Methylfolate Products, and recovery of Plaintiffs' costs of this action. Defendant Method's actions has been willful and has been undertaken with the purpose of deceiving consumers. Thus, Plaintiffs are entitled to an award of punitive damages.

62. As a result of Defendant Method's conduct, Plaintiffs have suffered, and unless such acts and practices are enjoined by this Court, will continue to suffer, damage to their business, reputation and goodwill for which they are entitled to relief.

IV. JURY DEMAND

Plaintiffs demand a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

A. The Court enter a judgment and an order temporarily, preliminarily and permanently enjoining Defendant, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with it, from directly or indirectly falsely or misleadingly advertising or promoting Defendant's L-Methylfolate Products or inducing others to substitute Defendant's L-Methylfolate Products for prescriptions written for the NHS Products;

B. The Court enter a judgment and an order temporarily, preliminarily and permanently enjoining Defendant, its agents, servants, employees, attorneys, successors and assigns, and all others in active concert or participation with it, from making or inducing others to make any false, misleading or deceptive statement of fact, or representation of fact in connection with the promotion, advertisement, display, sale, offering for sale, manufacture, production, circulation or distribution of Defendant's L-Methylfolate Products in such fashion as to suggest that Defendant's L-Methylfolate Products have the same ingredients in the same amounts as Plaintiffs' L-Methylfolate Products; are generic or equivalent to Plaintiffs' L-Methylfolate Products; can be freely interchanged with or substituted for prescriptions written for the NHS Products; or are drugs;

C. The Court enter a judgment and an order requiring Defendant to take corrective action to correct any erroneous impression persons may have derived concerning the nature, characteristics or qualities of Defendant's L-Methylfolate

Products, including without limitation the placement of corrective advertising;

D. The Court enter a judgment and an order granting Plaintiffs such other relief as the Court may deem appropriate to prevent the trade and public from deriving any erroneous impression concerning the nature, characteristics, qualities or benefits of Defendant's L-Methylfolate Products in comparison to Plaintiffs' L-Methylfolate Products;

E. The Court enter a judgment and an order requiring Defendant to pay Plaintiffs' damages in the amount of Plaintiffs' actual and consequential damages resulting from Defendant Method's false and misleading advertisements and marketing and unfair competition pursuant to 15 U.S.C. § 1117(a), and the common law of the State of Texas, and any profits resulting from Defendant's advertisements and marketing of its products;

F. The Court enter a judgment and an order finding that that this is an exceptional case and requiring Defendant to pay Plaintiffs additional damages equal to three times the actual damages awarded Plaintiffs pursuant to 15 U.S.C. § 1117(a);

G. The Court enter a judgment and an order finding that Defendant acted maliciously, wantonly and/or fraudulently, requiring Defendant to pay Plaintiffs punitive damages pursuant to the common law of the State of Texas;

H. The Court enter an order finding that this case is an exceptional case and requiring Defendant to pay all of Plaintiffs' reasonable attorneys' fees, costs and expenses, including those available under 15 U.S.C. § 1117(a), and any other applicable law;

I. The Court enter a judgment and an order requiring Defendant to pay Plaintiffs pre-judgment and post-judgment interest on the damages awarded; and

J. The Court enter a judgment and an order awarding Plaintiffs such other and further relief as the Court deems just and equitable.

Dated: May 12, 2015

Respectfully submitted,

s/Brett C. Govett

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